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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,534	11/28/2000	Merrill Goldenberg	A-576C	5310

7590 03/06/2003

U.S. Patent Operations/ CAC  
Dept. 4300, M/S 27-4-A  
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/728,534

Applicant(s)

GOLDENBERG ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 8 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. Claims 6-7 and 9-12 have been cancelled, claims 1-5 and 8 have been amended and claim 13 has been added as requested in the amendment of Paper No. 8, filed on December 23, 2002. Claims 1-5, 8 and 13 are pending and under consideration in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on December 23, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### *Double Patenting*

5. Claims 1-5, 8 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 108 of U. S. Patent No. 6,245,740 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons of record as applied to claims 1-12 in section 11 of Paper No. 7.

Applicant submits that because of the amendment of the claims "as to specify that the compositions are prepared from a solution of G-CSF" as compared to the compositions prepared from G-CSF powder in '740 patent, then "[s]uch claims, if allowed, would not improperly extend the "right to exclude already granted in the patent" (page 8, second paragraph of the Response). This has not been found to be persuasive for the following reasons.

One of ordinary skill in the art readily understands that in order to prepare a G-CSF: polyol mixture it is reasonable to start with G-CSF solution rather than a powder because it would take less time and effort to mix these two ingredients together. It is also well known that sometimes G-CSF is available from the manufacturer as a solution, which was the case in Example 14, page 28 of the instant specification. Furthermore, it is also obvious that because the claimed composition is intended for pharmaceutical use, the proper dilution of the concentrated stock would be in order. There is no scientific reasoning known to suggest that a solution prepared from a concentrated solution of G-CSF and neat polyol would have different properties than a solution prepared from powdered G-CSF and, for example, 75% glycerol (Table 2, page 29 of the instant specification). Moreover, if polyol is represented by a fructose or sucrose, which can be presented in a form of a powder itself, it is not clear how to prepare a solution of G-CSF: fructose but by dissolving G-CSF first.

*New grounds of rejection necessitated by amendment*

*Claim Rejections - 35 USC § 112*

6. Claims 1-5, 8 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claims 1 and 8 are vague and indefinite because it appears that the claims use terms "solution" and "mixture" interchangeably. It is clear from the instant specification that concentrated G-CSF solution was mixed with volumes of neat glycerol or different aqueous solutions of glycerol to prepare G-CSF/glycerol solutions (page 28, lines 9-25 and page 29,

Table 2 of the instant specification). Furthermore, it is stated in the Response that “a solution of G-CSF could be mixed with pure glycerol to form a G-CSF: glycerol suspension” (page 7, last paragraph of the Response). Therefore, it is not clear what physical form of G-CSF/glycerol composition is intended by the claims. Clarification is required.

Claims 1 and 8 are further indefinite for recitation “a solution of G-CSF”. There is no identification of a solvent and, therefore, the metes and bounds of the recitation cannot be determined from the claims or the instant specification.

8. Claims 2-5 and 13 are indefinite for being dependent from indefinite claims.

### *Conclusion*

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices

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published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
March 4, 2003



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800